REMARKS

Claims 17-26 are pending in this application. Claims 1-16 have been cancelled without prejudice to or disclaimer of the subject matter therein. Claims 17-26 have been newly added.

Claims 17 and 23 have been added to rewrite claims 7 and 13, now cancelled, in independent claim form. Claims 18-22 and 24-26 rewrite claims 2-6 and 9-13, now cancelled, as dependent claims from claims 17 and 23. Support for the amendment can be found throughout the specification and the claims as originally filed.

The amendments and cancellation of claims are solely for advancing prosecution. Applicants, by amending or cancelling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert the original claim scope of any claim amended herein, in a continuing application.

No new matter has been introduced to this application within the meaning of 35 U.S.C. §132.

In view of the following, further and favorable consideration is respectfully requested.

I. Priority

Applicants thank the Examiner for the acknowledgement of priority at page 2 of the Official Action. Pursuant to the Examiner's request, submitted herewith is a certified copy of the priority document, KR 10-2004-0021601, under 35 USC 119(b). An English translation of the priority application, along with a Statement

of Accuracy, is also attached.

II. At page 4, claims 7 and 13 are rejected under 35 USC §112, second paragraph, as being indefinite for their claim form.

Applicants submit that rejected claims 7 and 13 have been cancelled in the present application, and added as independent claims 17 and 23. Withdrawal of this rejection is, therefore, respectfully requested.

IV. At page 5 of the Official Action, claims 7 and 13 are rejected under 35 USC §102(b) and §102(e) as being anticipated by Hirsch et al (U.S. Publication No. 2003/0003583).

As a basis for the rejection, the Examiner indicates in relevant part of the Official Action that "*Hirsch et al.* disclose a method of delivering a gene into cells for the treatment of cancer [0151], the method comprising the use of an adenoviral gene delivery system [0019], wherein the gene may encode Relaxin [140]." In addition, the Examiner indicates that "Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. see MPEP §201.15."

Applicants respectfully traverse these rejections. In this regard, Applicants note that the test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. R*ichardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged

as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

In the present application, Applicant initially submit that as requested by the Examiner, an English translation of the priority application, KR 10-2004-0021601, is attached hereto along with a certified copy of the priority document. However, Applicants note that cited reference US Pub. No. 2003/0003583 to *Hirsch et al* is not an "intervening reference" as provided by MPEP §201.15.

Regarding the Examiner's assertion of anticipation, Applicants submit that presently pending claims 17-26 are not anticipated by US Pub. No. 2003/0003583 to *Hirsch et al.*, since *Hirsch et al.* fail to disclose each and every element of the pending claims, particularly independent claims 17 and 23.

Claim 17 is directed to a method for delivering a gene into cells, which comprises contacting a gene delivery system comprising a nucleotide sequence of interest to be delivered into a cell, to a biosample containing cells, wherein the gene delivery system comprises a relaxin-encoding nucleotide sequence to enhance a transduction efficiency of the nucleotide sequence of interest into the cell. Claim 23 is directed to a method for treating a cancer, which comprises administering to an animal a pharmaceutical anti-tumor composition comprising (a) a therapeutically effective amount of a recombinant adenovirus comprising an adenoviral ITR (inverted terminal repeat) nucleotide sequence and a relaxin-encoding nucleotide sequence; and (b) a pharmaceutically acceptable carrier; wherein a relaxin protein expressed enhances a penetration potency of the recombinant adenovirus into a tumor tissue and apoptosis of a tumor cell infected with the recombinant adenovirus. The other pending claims, namely claims 18-

22 and 24-26, are directly or indirectly dependent from claim 17 or claim 23.

Hirsch et al. describe methods for using adeno-associated virus for transduction of a target gene in a variety of tissues wherein the expression of the transgene is regulated by administration of a proteasome inhibitor. *Hirsch et al.* further describe that a therapeutic gene can be delivered *in vivo* by an adeno-associated virus to a tissue that is not normally transduced by adeno-associated virus; the host would then be administered a proteasome inhibitor in order to induce expression of the therapeutic gene. *Hirsch et al.* describe that the proteasome inhibitor is administered only when gene expression is desired. With regard to the target gene, *Hirsch et al.* describes various potential genes that can be used for the disclosed methods, from paragraph [0138] to paragraph [0141], one of them being relaxin.

However, *Hirsch et al.* do ***not*** disclose a gene delivering method using the construct comprising "a nucleotide sequence of interest to be delivered and a relaxin-encoding nucleotide sequence," ***nor*** do they disclose "a novel use of relaxin to enhance a transduction efficiency of a target nucleotide sequence," as required by present claim 17. The description of relaxin at paragraph [0140] of *Hirsch et al.* only suggests a possible use of relaxin in the method disclosed therein, as a potential "target gene," but not for the use to enhance a transduction efficiency of a target gene. No teaching or suggestion of the use of relaxin to enhance a transduction efficiency of a target gene is found in *Hirsch et al.* Accordingly, *Hirsch et al.* fail to disclose each and every element of present claim 17 and its dependent claims 18-22, as required by *Verdegaal Bros. v. Union Oil*

Co. of California.

In addition, with regard to present claim 23, *Hirsch et al.* fail to disclose a method for treating cancers where relaxin is used "to enhance a penetration potency of a recombinant adenovirus into a tumor tissue and apoptosis of a tumor cell infected with the recombinant adenovirus," as recited by present claim 23.

As aforementioned, *Hirsch et al.* disclose relaxin as one of the target genes to be carried in a recombinant adeno-associated virus. In addition, *Hirsch et al.* generally disclose cancers as one of a wide variety of potential conditions for which the method disclosed therein may be used. It should be noted that such disclosure of *Hirsch et al.* is dependent on the type of target genes carried in a recombinant adeno-associated virus. For instance, if the target gene carried in the recombinant adeno-associated virus is a therapeutic gene for cancers, the recombinant adeno-associated virus may be used to treat cancers as disclosed in *Hirsch et al.*

However, *Hirsch et al.* do not disclose that the recombinant adeno-associated virus carrying the relaxin gene is useful in treating cancers. Moreover, *Hirsch et al.* do not disclose that relaxin can be used to enhance a penetration potency of a recombinant adenovirus into a tumor tissue and apoptosis of a tumor cell infected with the recombinant adenovirus in treating cancers. Moreover, *Hirsch et al.* disclose a recombinant adeno-associated virus (i.e., recombinant AAV virions free of both wild type AAV and infectious helper virus) being different from a recombinant adenovirus as required by present claim

23. Accordingly, *Hirsch et al.* fail to disclose each and every element of present claim 23, i.e., a recombinant adenovirus, and a novel use of relaxin to enhance a penetration potency of a recombinant adenovirus into a tumor tissue and apoptosis of a tumor cell infected with the recombinant adenovirus in method for treating cancers, as required by *Verdegaal Bros. v. Union Oil Co. of California.*

Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

CONCLUSION

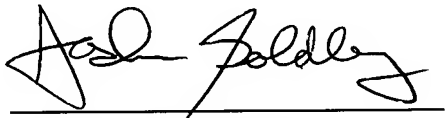
In view of the foregoing, Applicants submit that the pending claims are in condition for allowance. Early notice to this effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application.

If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

In the event this paper is not timely filed, applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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